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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,552	SCHROEDER ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed July 2, 2004 has been entered.

Claims 1-24 are pending.

Claims 15-24 are withdrawn.

Claims 1-14 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed January 30, 2004.

Applicants' arguments filed July 2, 2004, have been fully considered but they are not persuasive.

Applicants point out that as of the application's priority date literally scores of peptide and peptidomimetic inhibitors of farnesyltransferase were known in the art, and Applicants point in particular to two references cited in the previous office action, Reiss et al., Cell 62:81-88 (1990) (hereafter, "Reiss") and Tamanoi, TIBS 18:349-353 (1993) (hereafter, "Tamanoi"), as teaching such inhibitors. Applicants further point to the disclosure as reciting no fewer than 10

patents (incorporated by reference) that issued on novel farnesyltransferase inhibitors between just 1998 and the filing of the priority international application in September 1999. Applicants assert that they, like others in the art, had possession of a large number of inhibitors of farnesyltransferase at the time of filing. Applicants also assert that *Lily* does not apply to the instant situation, because in *Lily* the patent holder claimed a human cDNA sequence that was not disclosed in the application or the prior art, whereas the sequences at issue here were known for years before filing. Applicants additionally assert that given the dictate that the specification does not need to set forth, and preferably omits, information that would be known to persons of skill in the art, it was unnecessary for Applicants to recite specific sequences in the specification merely to convey how that they also had a copy of the genetic code and could convert the peptide sequences into corresponding nucleic sequences. (reply pages 2-7)

The rejection is maintained because the claims are not directed to inhibitors of farnesyltransferase per se. The claims are directed to a method of inhibiting farnesyltransferase in a plant by transforming a plant with said expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor, and a plant comprising an expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor. Neither the specification nor the prior art describe nucleic acid sequences encoding proteins whose expression would inhibit farnesyltransferase in a plant transformed therewith, i.e. inhibitors of farnesyltransferase that would function to inhibit farnesyltransferase in a plant upon expression in vivo. Both "Reiss" and "Tamanoi", cited in the previous office action, as well as the patents cited by Applicants, refer only to inhibitors of farnesyltransferase that are known to function to inhibit farnesyltransferase in vitro, or in nonplant, e.g. mammalian, in vivo systems; they make

no reference to farnesyltransferase inhibitors that would function to inhibit farnesyltransferase when expressed in plant cells.

Claims 1-14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed January 30, 2004.

Applicants' arguments filed July 2, 2004, have been fully considered but they are not persuasive.

Applicants assert that the previous office action does not meet the burden of establishing a reasonable basis to question the enablement provided for the claimed invention. Applicants assert that the action cites no cases or art showing that there is any unpredictability in the activity of farnesyltransferase inhibitors generally or specifically as applied to the case of inhibiting farnesyltransferase in plants. Applicants further assert that the action points to no particular reason that expression of farnesyltransferase inhibitors would require more than routine experimentation to adapt standard methods to permit expression of the inhibitors, and that the Action appears to assume that, if any experimentation is required, the invention is not enabled. Applicants point out that an invention can require considerable experimentation to practice so long as that experimentation is not undue, and point to *In re Wands* as articulating the criteria for determining whether experimentation is undue. Applicants assert that the action does not even acknowledge the *Wands* factors, let alone indicate that there is any reason that the application

does not satisfy them, and assert that the Action is therefore grounded on an incorrect basis and should be withdrawn on this basis alone. (reply pages 8-9)

The rejection is maintained because the claimed invention is not enabled. With respect to Applicants' assertion that the previous action cites no cases or art showing that there is any unpredictability in the activity of farnesyltransferase inhibitors generally, the Examiner maintains that such cases or art need not be cited, as the outstanding rejection is not predicated on the unpredictability in the activity of farnesyltransferase inhibitors generally. With respect to Applicants' assertion that the previous action cites no cases or art specifically as applied to the case of inhibiting farnesyltransferase in plants, the Examiner maintains that the prior art of record does not disclose inhibiting farnesyltransferase in plants by transforming plants with polynucleotides encoding farnesyltransferase inhibitors. With respect to Applicants' assertion that the previous action points to no particular reason that expression of farnesyltransferase inhibitors would require more than routine experimentation to adapt standard methods to permit expression of the inhibitors, the Examiner maintains that Applicants' invention is not merely directed to the expression of farnesyltransferase inhibitors; Applicants' invention is directed to a method of inhibiting farnesyltransferase in a plant. With respect to Applicants' assertion that the previous action does not explicitly acknowledge the *Wands* factors by name, the Examiner maintains that the conclusion of nonenablement does not require explicit reference to the *Wands* factors by name, but rather the conclusion requires the consideration of all of the evidence in relation to each of these factors, with the conclusion being based on the evidence as a whole. With respect to Applicants' assertion that the previous action does not indicate that there is any

reason that the application does not satisfy the *Wands* factors, Applicants' attention is directed to the specific responses set forth below.

Applicants further maintain that application of the *Wands* criteria to the present claims shows that persons of skill in the art were fully enabled to use the invention as claimed without undue experimentation. With respect to factor 1 (the breadth of the claims), Applicants assert that the claims are narrowly drawn to plants expressing recombinant expression cassettes encoding inhibitors of a specific enzyme and to methods of inhibiting that enzyme in plants by introducing such recombinant expression cassettes (reply page 9).

With respect to factor 1 (the breadth of the claims), the Examiner disagrees that the claims are narrowly drawn. The target of inhibition is not the only claim limitation relevant to the breadth of the claims. The expression cassettes whose expression inhibits the target enzyme are also relevant to the breadth of the claims. As indicated at page 5 of the previous office action, the claims are broadly drawn to a plant comprising an expression cassette comprising a nucleic acid sequence encoding any farnesyltransferase inhibitor of unspecified structure and function, including any unspecified protein inhibitor.

With respect to factor 2 (the nature of the invention he invention), Applicants assert that is related to the surprising discovery that inhibition of farnesyltransferase activity in plants results in increasing their resistance to drought (reply page 9).

The Examiner notes that the claims do not require that inhibition of farnesyltransferase activity in plants result in increasing their resistance to drought. Further, the Examiner maintains

that the specification does not establish that inhibition of farnesyltransferase activity in plants has this result.

With respect to factor 3 (the state of the prior art), Applicants assert that the state of the prior art sets forth significant teachings on inhibitors of farnesyltransferase, as well as disclosing numerous promoters were known in the art for driving expression of nucleic acids in plants (reply pages 9-10).

The Examiner does not dispute that the prior art sets forth significant teachings on inhibitors of farnesyltransferase per se, and their use in nonplant, e.g. mammalian, in vivo systems, as well as disclosing numerous promoters were known in the art for driving expression of nucleic acids in plants. The Examiner notes, however, that the outstanding rejection was not predicated on the failure of the prior art to disclose inhibitors of farnesyltransferase per se, or on the failure of the prior art to disclose promoters for driving expression of nucleic acids in plants. The outstanding rejection was predicated on the failure of the specification to provide sufficient guidance with respect to which particular farnesyltransferase inhibitor to express, and with respect to how to express that farnesyltransferase inhibitor at concentration effective to confer a useful phenotype on a transgenic plant, in view of what the prior art teaches with respect to farnesyltransferase inhibitors.

With respect to factor 4 (the level of one of ordinary skill), Applicants assert that persons of skill in this art are typically Ph.D. plant scientist, that therefore the level of skill in the art is

very high, and that the amount of guidance that needs to be provided is correspondingly limited (reply page 10).

The Examiner does not dispute that the level of skill in the art is very high. The Examiner maintains, however, that while the general methodology required to transform plants is undisputedly within the abilities of one of skill in the art, the ability of one skilled in the art to readily transform plants does not compensate for the lack of guidance provided by the specification with respect to which particular farnesyltransferase inhibitor to express, and with respect to how to express that farnesyltransferase inhibitor at concentration effective to confer a useful phenotype on a transgenic plant, because such guidance is not elsewhere available to one skilled in the art, i.e. such guidance is not available in the prior art.

With respect to factor 5 (the level of predictability in the art), Applicants assert that substantial predictability can be found in the relevant field. Applicants point out that, as noted in the specification, techniques for transforming plants by various techniques were known and used for some 15 years prior to the priority date of the application (reply page 10).

While substantial predictability can be found in the relevant field with respect to transforming plants per se, the claimed invention is not directed to transforming plants per se. The claimed invention is directed to a method of inhibiting farnesyltransferase in a plant by transforming a plant with an expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor of unspecified structure and function, and a plant comprising said expression cassette. Furthermore, the outstanding enablement rejection was not predicated on the unpredictability of transforming plants per se. The outstanding enablement rejection was

predicated on the unpredictability of the effect of expressing a nucleic acid encoding a farnesyltransferase inhibitor in a plant (pages 5-6 of the office action mailed January 30, 2004).

With respect to factor 6 (the amount of direction provided by the inventor), Applicants assert that the specification provides ample guidance as to how to make and use the invention as claimed. Applicants point out that, for example, the specification teaches the preparation of recombinant vectors, suitable promoters, and production of transgenic plants. Further, Applicants point out that the specification contains an example of the production of fusion constructs and of production of transgenic plants, using the well-known GUS reporter gene.

As discussed above, the claimed invention is not directed to transforming plants per se. The claimed invention is directed to a method of inhibiting farnesyltransferase in a plant by transforming a plant with an expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor of unspecified structure and function, and a plant comprising said expression cassette. Furthermore, the outstanding enablement rejection was not predicated on the failure of the specification to provide guidance with respect to plant transformation per se. The outstanding enablement rejection was predicated on the failure of the specification to provide guidance with respect to which particular farnesyltransferase inhibitor to express, and with respect to how to express that farnesyltransferase inhibitor at concentration effective to confer a useful phenotype on a transgenic plant (see pages 5-6 of the office action mailed January 30, 2004).

With respect to factor 7 (the existence of working examples), Applicants assert that the specification sets forth a working example showing the expression of a transgene in *Arabidopsis* guard cells, and Applicants maintain that while the example relates to the expression of a reporter gene, the Action sets forth no reasoning or art showing that there would be any different result if the sequence encoding the reporter were to be replaced instead with a sequence encoding a farnesyltransferase inhibitor (reply page 10).

The claims are not directed to expression of a GUS reporter gene in *Arabidopsis* guard cells. Accordingly, the example referred to by Applicants is not considered to be a working example of the invention. The claims are directed to a method of inhibiting farnesyltransferase in a plant by transforming a plant with an expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor. The specification does not set forth even a single working example of transforming a plant with an expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor. Additionally, the protein product expressed by the GUS reporter gene (β-Glucuronidase) is not know or disclosed as being equivalent in function or effect to the protein product expressed by the claimed plants. Further, with respect to the prior office action not setting forth reasoning or art showing that whether there would be any different result if the sequence encoding the reporter were to be replaced instead with a sequence encoding instead a farnesyltransferase inhibitor, Applicants is directed to pages 5-6 of the action, which sets forth that the effect of expressing a nucleic acid encoding a farnesyltransferase inhibitor in a plant is unpredictable because expression methods must be specifically adapted in order to achieve a particular desired phenotype, as different levels of protein expression produce different phenotypes, because farnesyltransferase inhibition is dependent on inhibitor

concentration and further varies between different types of farnesyltransferase inhibitors, and because compounds that inhibit farnesyltransferase in vitro may be unstable in vivo. Also, Tamanoi (Trends Biochem Sci 1993 Vol. 18, No. 9, pages 349-353), Reiss et al. (Cell, 1990, Vol. 62, No. 1, pages 81-88), and Lerner et al. (Anticancer Drug Res 1997, Vol. 12, No. 4, pages 229-238) were cited at page 6 of the prior office action in support of these assertions.

With respect to factor 8 (the quantity of experimentation needed to make or use the invention based on the content of the disclosure), Applicants assert that the amount of experimentation necessary for an artisan to make or use the invention as claimed is modest. Applicants point to the previous paragraph, where it is noted that techniques and methodologies for expressing farnesyltransferase inhibitors are set forth in the specification, and assert that the specification thus sets forth all the information an artisan needs to express any particular farnesyltransferase inhibitor in any particular plant of interest. (reply pages 10-11)

The Examiner disagrees with Applicants' assertion that the amount of experimentation necessary for an artisan to make or use the invention as claimed is modest. The conclusion that undue experimentation would be required to practice the claimed invention was not predicated on the unpredictability of or lack of guidance with respect to techniques and methodologies for transgene expression in plants (plant transformation techniques and methodologies per se). Applicants' invention is not directed to merely expressing a farnesyltransferase inhibitor in a plant of interest. Applicants' invention is directed to inhibiting farnesyltransferase in a plant by transforming a plant with an expression cassette comprising a nucleic acid sequence encoding a farnesyltransferase inhibitor, and a plant comprising said expression cassette. Accordingly, the

conclusion that undue experimentation would be required to practice the claimed invention was predicated on the unpredictability of the effect of expressing a nucleic acid encoding a farnesyltransferase inhibitor in a plant, the lack of guidance with respect to which particular farnesyltransferase inhibitor to express, and the lack of guidance with respect to how to express that farnesyltransferase inhibitor at concentration effective to confer a useful phenotype on a transgenic plant (pages 5-6 of the office action mailed January 30, 2004).

Applicants assert that the previous office action appears to assume that if there is any variability and if any experimentation is required, the invention is not enabled, and Applicants maintain that this is not correct. Applicants point out that an invention can require considerable experimentation to practice so long as that experimentation is not undue, and that whether experimentation is undue is determined under the criteria set forth in *Wands*. Applicants reiterate that that the action does not acknowledge *Wands*, let alone indicate that there is any reason that the application does not satisfy them, and Applicants assert that the action is therefore grounded on an incorrect basis. Applicants observe that the action has set forth neither reasoning nor art indicating that producing farnesyltransferase inhibitors in plants would require any more experimentation than producing plants that express, for example, insect toxins from the bacterium *Bacillus thurengiensis*, and yet plants expressing such toxins are commercially available. Applicants assert that is indeed routine in the art to generate a number of transgenic plants, to select for those expressing the desired phenotype, and to bulk up seed production of plants with the desired phenotype. (reply pages 11-12)

The Examiner maintains that the previous office action does implicitly and repeatedly acknowledge *Wands* as set forth above, and does indicate specific reasons that the application does not satisfy them. With respect to producing plants that express insect toxins such as those from the bacterium *Bacillus thurengiensis* versus producing plants that express farnesyltransferase inhibitors, the Examiner maintains that the comparison is inapposite given the asserted basis for the enablement rejection. First, guidance for expressing insect toxins from the bacterium *Bacillus thurengiensis* is available in the prior art, as the prior art teaches which toxins to express and how to express them at concentration effective to confer a useful phenotype on a transgenic plant. The prior art provides no guidance with respect to which particular farnesyltransferase inhibitor to express or how to express that farnesyltransferase inhibitor at concentration effective to confer a useful phenotype on a transgenic plant. Second, insect toxins from the bacterium *Bacillus thurengiensis* are not know or disclosed as being equivalent in function or effect to the protein product expressed by the claimed plants, such that the guidance provided by the prior art with respect to expressing insect toxins from the bacterium *Bacillus thurengiensis* is not applicable to expressing farnesyltransferase inhibitors.

Applicants finally assert that the ground of unpredictability alleged in the prior office action with respect to the potential in vivo instability of farnesyltransferase inhibitor is simply inapplicable to the claims under examination. Applicant points in particular to the previously cited reference of Lerner et al. (Anticancer Drug Res 1997, Vol. 12, No. 4, pages 229-238), which by their discussion of increasing the stability of the tetrapeptides towards proteolytic degradation to increase their cellular uptake shows that Lerner was concerned with the exposure

of these tetrapeptides to proteases in human serum, that is, in the extracellular fluids, before the peptides are taken up by the target cells. Applicants point out that the farnesyltransferase inhibitors recited in the claims are expressed within cells, and are therefore not exposed to such extracellular fluids. Applicants maintain the previous action shows no nexus between Lerner's concerns about the stability of tetrapeptides administered into the circulation as anti-cancer agents and the expression of the same peptides within plant cells to inhibit stomatal opening. Applicants further assert that even assuming that plant tissues have endogenous proteases in extracellular fluids analogous to the proteases present in human serum -- which the Action neither alleges nor shows -- it would not constitute a showing that stability is an issue with regard to inhibitors expressed and acting within a cell. Applicants therefore maintain that this ground of alleged unpredictability is simply not applicable to the claims under rejection. (reply pages 12-14)

The ground of unpredictability alleged in the prior office action with respect to the potential in vivo instability of farnesyltransferase inhibitors is applicable to the claims under examination. With respect to the previously cited reference of Lerner, a distinction need not be made between the intracellular or extracellular location of expressed farnesyltransferase inhibitors, as it is the products produced by the cells themselves which are secreted into the extracellular environment which affect the stability of farnesyltransferase inhibitors. Accordingly, the farnesyltransferase inhibitors recited in the claims that are expressed within cells need not be exposed to extracellular fluids in order to potentially be affected by products that are produced by the cells themselves. With respect to a nexus between Lerner's concerns about the stability of farnesyltransferase inhibitors administered into the circulation as anti-

cancer agents and the expression of the same peptides within plant cells to inhibit stomatal opening, the Examiner maintains that such a nexus need not be established, as the claims are not directed to the inhibition of stomatal opening. With respect to a nexus between Lerner's concerns about the stability of farnesyltransferase inhibitors administered into the circulation as anti-cancer agents and the expression of the same peptides within plant cells, the Examiner maintains that the nexus established in the prior office action was that of the known potential for in vivo instability of certain farnesyltransferase inhibitors in animal systems, and the proposed in vivo use of farnesyltransferase inhibitors in the plant cell systems of the claimed invention. The Examiner further maintains that one skilled in the art would recognize the ubiquity of proteases in all known cellular systems, including plants.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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